

Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 8/24/2018 5:44:47 PM
To: Dunton, Cheryl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ffa0e71e87448cc9fd86ba1379ea93a-Dunton, Cheryl]
Subject: Re: Quote from you in NYT article today

Yes!

Nancy B. Beck, Ph.D., DABT
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Office of Chemical Safety and Pollution Prevention
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Personal Phone / Ex. 6
beck.nancy@epa.gov

On Aug 24, 2018, at 1:42 PM, Dunton, Cheryl <Dunton.Cheryl@epa.gov> wrote:

Oh ok, whew.

From: Beck, Nancy
Sent: Friday, August 24, 2018 1:42 PM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Subject: Re: Quote from you in NYT article today

Deliberative Process / Ex. 5

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
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On Aug 24, 2018, at 1:38 PM, Dunton, Cheryl <Dunton.Cheryl@epa.gov> wrote:

Deliberative Process / Ex. 5

<https://www.nytimes.com/2018/08/24/business/epa-pesticides-studies-epidemiology.html?action=click&module=Top%20Stories&pgtype=Homepage>

Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science'

Backed by agrochemical companies, the current administration and Congress are moving to curb the role of human health studies in regulation.

Aug. 24, 2018



A strawberry field in California's Salinas Valley, where a yearslong study, funded in part by the Environmental Protection Agency, has linked pesticides to ailments in children of farm workers. Carlos Chavarría for The New York Times

SALINAS, Calif. — José Camacho once worked the fields here in the Salinas Valley, known as “the Salad Bowl of the World” for its abundance of lettuce and vegetables. His wife still does.

But back in 2000, Mr. Camacho, who is 63, got an unusual phone call. He was asked if he wanted to work for a new project studying the effects of pesticides on the children of farm workers.

“This seemed really crazy,” he recalled saying at the time, since he barely spoke English. “A research study?”

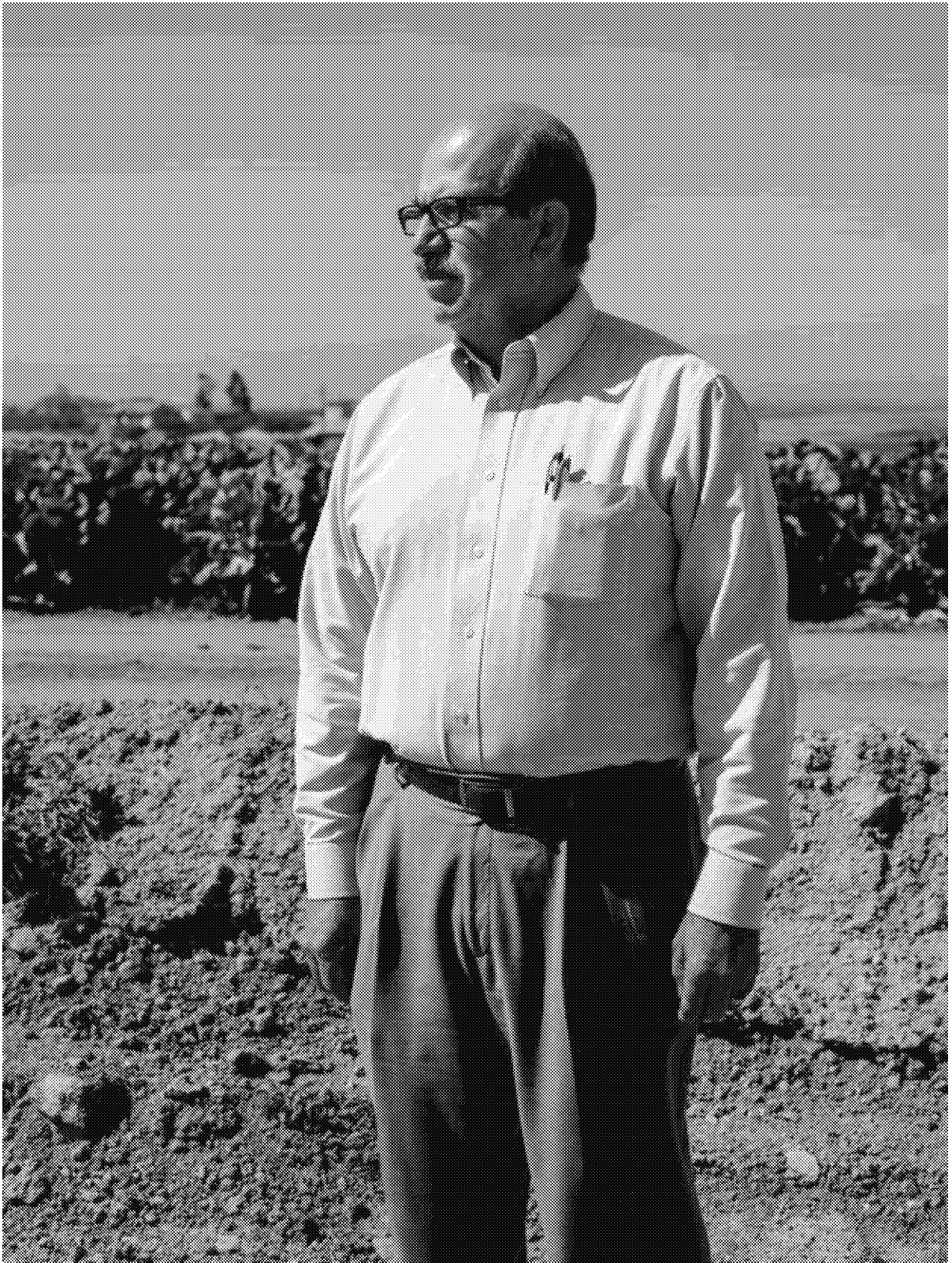
The project, run by scientists from the University of California, Berkeley, and funded in part by the Environmental Protection Agency, is still going all these years later. Known as Chamacos, Spanish for “children,” it has linked pesticides sprayed on fruit and vegetable crops with respiratory complications, developmental disorders and lower I.Q.s among children of farm workers. State and federal regulators have cited its findings to help justify proposed restrictions on everything from insecticides to flame-retardant chemicals.

But the Trump administration wants to restrict how human studies like Chamacos are used in rule-making. A government proposal this year, called Strengthening Transparency in Regulatory Science, could stop them from being used to justify regulating pesticides, lead and pollutants like soot, and undermine foundational research behind national air-quality rules. The E.P.A., which has funded these kinds of studies, is now labeling many of them “secret science.”

Studying disease trends in specific groups of people — a branch of medicine known as epidemiology — started to gain currency at the E.P.A. in recent years. These studies can be difficult because they require adjusting for all the various substances people are exposed to beyond pesticides. But researchers had amassed years of data from a wave of compelling chemical studies begun in the 1990s, giving regulators a new body of research to incorporate into their decision-making.

Under the Obama administration, the E.P.A., which had long favored tests on rats and other laboratory animals in its pesticide regulation, began considering epidemiological studies more seriously. The agency leaned on this type of research in proposing to ban an insecticide called chlorpyrifos in late 2016, and has been repeatedly prodded to take action on the chemical by federal courts.

But weeks after Donald J. Trump was elected president, CropLife America, the main agrochemical trade group, petitioned the E.P.A. to “halt regulatory decisions that are highly influenced and/or determined by the results of epidemiological studies” unless universities were forced to share more of their data.



José Camacho was asked in 2000 to participate in the study, which tracks families as they go about their normal lives. Such research was embraced by the E.P.A. during the Obama administration. Carlos Chavarría for The New York Times

Industry leaders aggressively challenged such studies in high-level meetings and emails with E.P.A. leaders, according to thousands of pages of documents obtained through Freedom of Information Act requests. One trade group invited a top E.P.A. official to meet with its Washington lobbyist last year, complaining that “carefully controlled” animal studies were giving way to “conclusions reflected in epidemiological papers.”

Gary W. Van Sickle, executive director of the California Specialty Crops Council, wrote to the agency last September that “there have been serious flaws with E.P.A.’s conclusion to use these data.”

The council, representing growers of crops as diverse as carrots, garlic, pears and peppers, cited “inappropriate use of the epidemiology.”

The E.P.A., whose new leadership is seeded with industry veterans, has responded. In a mid-July assessment of atrazine, a widely used weed killer long banned in Europe, the agency reviewed and dismissed 12 recent epidemiological studies linking the herbicide to such ailments as childhood leukemia and Parkinson’s disease. It echoed the conclusions of research funded by Syngenta, atrazine’s manufacturer, finding the chemical unlikely to cause cancer.

Before scandals forced Scott Pruitt out last month as head of the E.P.A., he proposed the transparency regulation. It would ban many epidemiological studies, and other outside research, unless more data behind the studies was made public. In doing so, he revived a strategy advanced for years by congressional Republicans and corporate interests like tobacco companies.

“The era of secret science at E.P.A. is coming to an end,” Mr. Pruitt proclaimed at the time. The agency’s new acting administrator, Andrew R. Wheeler, says he’s moving forward with the proposal, as the agency re-evaluates a class of widely used insecticides, called organophosphates, that have been the subject of numerous epidemiological studies like Chamacos.

Nancy B. Beck, a chemical industry veteran who is the E.P.A.’s deputy assistant administrator, said there was no attempt to thwart epidemiology, adding that the agency was committed to “the best available science in the most transparent manner.”

But academics and state health officials say universities are being pressured to release data that would ultimately divulge the identities of study

participants, a strategy once used by tobacco companies seeking to undermine research on the dangers of smoking. While participant data is shared with regulators in drug trials, academics fear that the E.P.A.'s proposal would additionally require divulging confidential personal information, potentially violating privacy regulations for federally funded research.



Ana Lilia Sanchez, a farm worker and the mother of a participant in the Salinas Valley study, said her family took precautions to avoid pesticide contamination. Carlos Chavarría for The New York Times

“It is a naked attempt to use a false claim that something nefarious is going on with these studies in an effort to allow industry to challenge conclusions that are not in their favor,” said James Kelly, a manager of environmental surveillance at the Minnesota Department of Health.

A Wave of Studies, an Uneasy Industry

An advertisement in a Nebraska student newspaper was looking for people who wanted to “earn extra money.” Thirty-six college student volunteers and others from the community who responded were paid \$460 to drink gelatin capsules filled with the pesticide chlorpyrifos, at up to 300 times levels the E.P.A. considered safe, without a full discussion of the risks.

Sponsored by Dow Chemical, this study, conducted in 1998, was one of the last of its kind. That year, the E.P.A. banned the use of studies exposing people to pesticides, and it continues to severely restrict them.

Epidemiology, which has been used to examine everything from the effects of climate change to childhood obesity, offered a way to continue studying disease trends, amid new legal requirements to examine how pesticides particularly affect infants and children. And it could do so by tracking people during their normal lives instead of treating them as if they were lab rats. Chamacos and other studies began almost immediately, although it took decades to collect sufficient data and study how participants changed over time.

One study by Columbia University researchers linked an insecticide to developmental delays in toddlers. Another, by scientists at the University of California, Los Angeles, connected pesticides to Parkinson's disease. Academics at the University of Rochester found that pesticides lower sperm counts in men, while researchers from the Harvard School of Public Health found lower fertility in women.

By 2015, there was a growing body of research, often funded in part by the E.P.A. The agency decided that year to consult epidemiology more seriously in its evaluation of glyphosate, the world's most popular weed killer and the active ingredient in Monsanto's Roundup.

"This is a watershed event in our Program, and one which I feel particularly proud to be a part (go epi!!)," Carol Christensen, then an E.P.A. epidemiologist, wrote in a 2015 email to a colleague — using "epi" as shorthand for epidemiology. "In the 35 year history of our program, this will be the FIRST time epi studies are actively considered in the decision making."

Yet even then, there was friction over what to make of studies aiming to determine whether glyphosate causes cancer.

One E.P.A. division, the Office of Research and Development, closely examined epidemiological research and came to believe either that glyphosate was likely to cause cancer or that there was at least some evidence suggesting a problem. But another division, the Office of Pesticide Programs, was dismissive of epidemiological studies and determined that glyphosate was not a carcinogen, a view that prevailed at

the E.P.A., according to interviews, emails and an internal memo obtained by The New York Times. Those involved in the agency's debates on epidemiology spoke on the condition of anonymity because the discussions weren't public.

Monsanto said in a statement that "we cannot speak to the internal E.P.A. discussions" but emphasized the agency's ultimate finding that glyphosate was not likely to cause cancer.

The cancer question received renewed attention this month when a California jury awarded \$289 million to a groundskeeper who alleged that the chemical had sickened him. In his closing argument, the plaintiff's attorney, R. Brent Wisner, called epidemiology one of "the three pillars of cancer science" that the case relied on.

At the E.P.A., the debate swung in favor of epidemiology. While such studies are often complex and can be of varying quality, the agency was reluctant in the past to give them as much weight as lab experiments on animals. But by the Obama administration's final months, the agency moved for the first time to ban a pesticide largely because of epidemiological research.

The pesticide, chlorpyrifos, was the same one ingested years earlier by unwitting Nebraskans. It is applied to crops like apples, oranges and strawberries to combat insects like spider mites and sap-sucking bugs.

In California alone, chlorpyrifos was sprayed on 640,000 acres in 2016, according to state data. And research from Salinas, and the Chamacos study, became a central element in the E.P.A.'s recommendation.

"There is a breadth of information available on the potential adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos," the agency concluded in 2016, also citing epidemiological research from Columbia University and the Icahn School of Medicine at Mount Sinai.

The pesticide industry's reaction was loud and intense.

Monsanto, in emails with the E.P.A., was dismissive of critical epidemiological research related to Roundup, writing that "such studies are well known to be prone to a number of biases."



A Trump administration proposal would prevent the E.P.A. from using many epidemiological studies, like the one in Salinas, unless more data behind them was made public. Carlos Chavarria for The New York Times

Dow Chemical said in reports submitted to the E.P.A. that “the evidence from these studies is insufficient” and called chlorpyrifos a “proven first-line of defense” against new pest outbreaks.

A month after taking over the E.P.A., Mr. Pruitt acted. He disregarded agency scientists and rejected the proposed chlorpyrifos ban, later calling for “a new day, a new future, for a common-sense approach to environmental protection.”

View From the Field

Ana Lilia Sanchez, 50, has worked in the fields in Salinas more than half her life, and one of her daughters has been a Chamacos study participant.

Ms. Sanchez has learned to watch for drifting droplets or the whirl of a helicopter spraying overhead.

“Sometimes when we feel it, or we hear it, we start talking about it,” she said recently, sitting with her 5-month-old granddaughter at her home on a Salinas cul-de-sac. “Why wouldn’t they tell us, you know, to get out of

here, to not come today?” she asked. “Women, they cover themselves, but men are working in short sleeves, so they are more exposed.”

Insecticides like chlorpyrifos are organophosphates, from the same chemical family as nerve agents like sarin and Novichok, the Russian-developed compound linked to recent attacks in Britain. While the safety of insecticides is extensively tested, long-term health impacts, or even how far pesticides drift, are the subject of continuing disagreement.

Ms. Sanchez showers after work, before touching her granddaughter.

“I also put my clothes aside,” she said. “We separate the clothes we use when we’re working, both my husband and I, and wash them separately so they’re not contaminated.”

While some human studies examine potential harm from pesticide residue found on fruits and vegetables, the Chamacos project is more personal, following hundreds of children in the heart of where American food is grown. California has the nation’s largest agricultural industry and uses more than 200 million pounds of pesticides annually.



Brenda Eskenazi, the director of the Salinas Valley project, said that “well-controlled epidemiologic studies” were essential for understanding “how things affect human health.” Carlos Chavarria for The New York Times

For locals, pesticides are part of life. “It’s a big difference from when I was working,” Mr. Camacho said, while standing in a strawberry field framed on three sides by distant hills. Men and women were bent over nearby, pulling weeds. “My supervisor would say: ‘That’s not dangerous. Just keep working.’ There was no information.”

Chamacos is built on an unsettling premise: What happens to children of pregnant mothers certain to have pesticides in their bloodstreams? The E.P.A. and other government agencies have spent millions of dollars funding Chamacos.

Half the Chamacos children have been tracked since before birth. Researchers have collected 350,000 samples of blood, urine, breast milk and even household dust and spent nearly two decades studying maturing children. They perform neurodevelopmental and physical assessments and study factors like diet and school performance. After nearly two decades, the study’s data appears in more than 160 academic papers.

During a visit to the Chamacos office in Salinas, Brenda Eskenazi, the director of the project and a professor of epidemiology at Berkeley, was testing out brain monitoring equipment, wearing what looked like a black swim cap strewn with knobs and wiring. She has long been fascinated with cognitive development, going back to when she saw a Woodstock reveler — one having a bad acid trip — dive into pavement.

“Why did he do that?” Ms. Eskenazi remembers wondering at the time. “What was he thinking? What’s going on in that brain?”

“Any science is imperfect,” she said, but stressed that “well-controlled epidemiologic studies” were essential for understanding “how things affect human health.” She added, “Otherwise you’re just making huge assumptions that a rodent is the same as a human.”

A Bitter Debate

The day after Mr. Pruitt made his March 2017 decision to reject a ban on chlorpyrifos, he hosted top executives from one of the nation's largest farming and pesticide trade organizations for a closed-door conversation.

Near the top of the meeting agenda was "Epidemiology Study Policy" in the aftermath of the "chlorpyrifos matter," according to internal records.



McKinnon Elementary School in Salinas. The pesticide industry contends that epidemiological studies are prone to biases and not as reliable as testing on lab animals. Carlos Chavarría for The New York Times

"There are no guideposts, if you will, for what is a legitimate, useful epidemiology study and what is not," Jay Vroom, CropLife America's president, said in an interview, explaining what he had told agency officials at this and other meetings.

In a subsequent letter to the E.P.A., a CropLife America lobbyist said the agency was relying on a "shortsighted approach," and the group submitted formal proposals to curb the embrace of epidemiology the E.P.A. undertook under the Obama administration.

Mr. Pruitt responded with his proposal, made this past spring, to ban epidemiological and other studies that did not make study details public, including at least some information on study participants.

Academics have resisted previous requests to review their data, notably at Columbia University. In a 2016 letter to the agency, a university official wrote that it could not provide “extensive individual level data to E.P.A. in a way that ensures the confidentiality” of “our research subjects.”

David Michaels, an epidemiologist at George Washington University’s School of Public Health and head of the Occupational Safety and Health Administration during the Obama administration, said Mr. Pruitt’s plan was not about transparency but about discrediting studies that made pesticides look bad.

“The underlying justification for this ‘transparency’ proposal is a caricature of how science really works,” Mr. Michaels said at a recent hearing. “The cynical approach proposed by E.P.A. can be best described as ‘weaponized transparency.’”

It is no coincidence, he said, that the term “secret science” was also used in the 1970s when the tobacco industry was trying to forestall critical research about smoking.

Researchers have had wins. This month, a federal appeals court ordered the E.P.A. to ban chlorpyrifos, citing findings from human studies. The Trump administration is mulling whether to appeal.

But epidemiologists are unsettled. In mid-July, after nearly two decades of work on Chamacos, the E.P.A. emailed Ms. Eskenazi requesting “the original data” from her research, citing “uncertainty around neurodevelopmental effects associated” with pesticides she has studied. The agency made a similar request to Columbia.

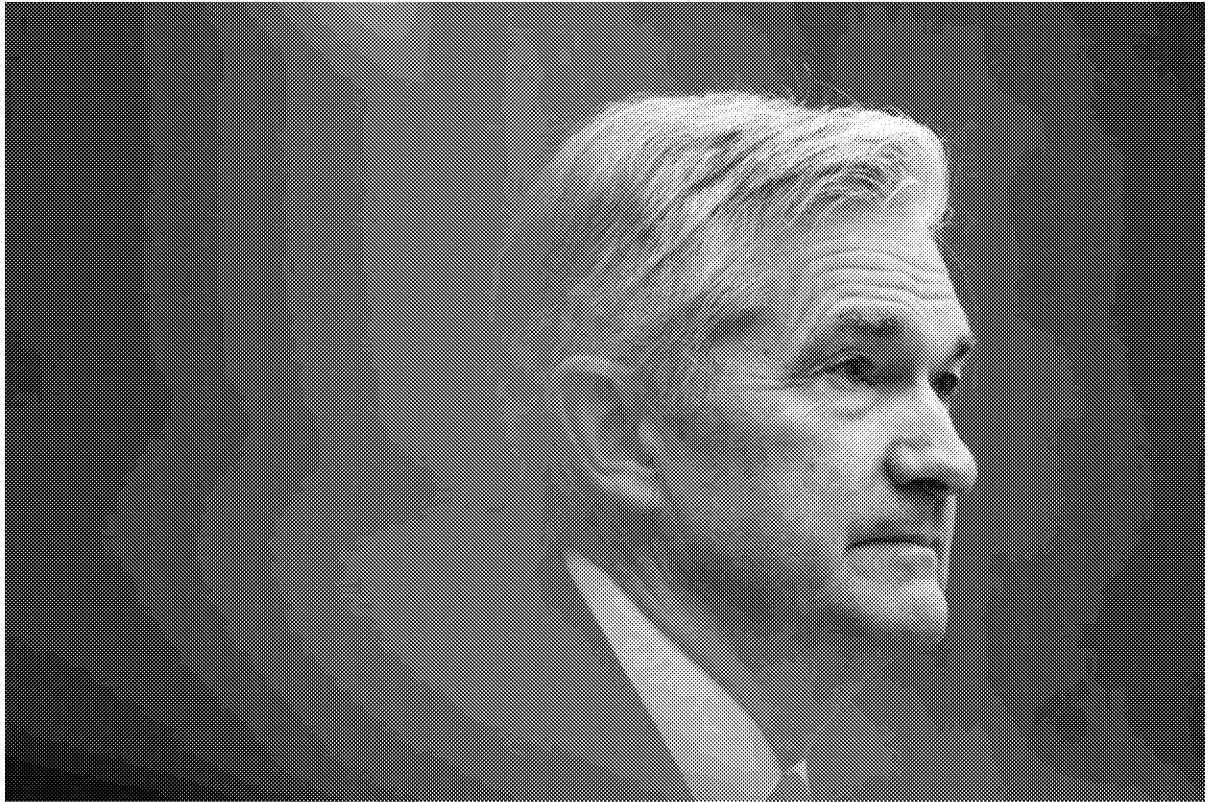
Ms. Eskenazi, worried about her study participants’ privacy, alerted university lawyers. She is now concerned that the E.P.A. may try to undermine her study’s repeated findings that some pesticides may be harming children.

“I knew this was going to come sooner or later,” she said. “And here it is.”

Danny Hakim reported from Salinas, and Eric Lipton from Washington.

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